



VIA FEDERAL EXPRESS

Food and Drug Administration 555 Winderley Pl., Ste. 200 Maitland, Fl 32751

Ref: Customs Entry No: 608-0822626-4/001

Product: · Ivomec Animal Antibiotic (240 pcs)

WARNING LETTER

FLA-01-35

February 15, 2001

Jean Michel Lopez, President Micro Worldwide Trading 8600 N.W. South River Drive Ste. 159 Miami, Florida 33166-7434

Dear Mr. Lopez:

The Food and Drug Administration (FDA) attempted to examine a shipment of Ivomec animal antibiotic offered for entry into the United States by your firm on November 15, 2000, under the above referenced entry number, and found that the entire shipment was not available for FDA examination. Title 21, Code of Federal Regulations (21CFR), Section 1.90 requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. Since the product was not held intact, we have requested the U. S. Customs Service (Customs) to order redelivery of the animal antibiotic which have been distributed without a release from FDA (copy enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of further shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter outlining the specific steps you have taken to correct the violation. Your response should include an explanation of each step being taken to prevent the recurrence of the violation. In the event that the product is still available for examination, you should inform Customs and FDA if and when redelivery is accomplished.

Jean Michel Lopez Page 2 February 15, 2001

Your written reply should be addressed to the Food and Drug Administration, Attention: Paul R. Bagdikian, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

Emma R. Singleton
Director, Florida District

cc: Port Director

U. S. Customs Service

P. O. Box 02-580

Miami, Florida 33102-5280

Total Port Clearance of Florida, Inc. 8725 N.W. 18th Terrace, #209